

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ion of:

Rothman et al.

Confirmation No.:

3143

Application No.:

10/053,520

Art Unit:

1646

Filed:

January 17, 2002

Examiner:

Basi, Nirmal Singh

For:

CONJUGATE HEAT SHOCK PROTEIN

BINDING PEPTIDES

Attorney Docket No.: 8449-429-999

REPLACEMENT INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.56 AND § 1.97

Mail Stop Amendment **Commissioner for Patents** P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby direct the Examiner's attention to references B01-B15 and C01-C78, which are listed on the attached List of References Cited by Applicant. Copies of references B01-B15 and C01-C78 are submitted herewith.

This Information Disclosure Statement ("IDS") replaces the IDS submitted May 12, 2003 in connection with the above-identified application. This Replacement IDS is submitted for the purpose of providing to the PTO copies of the references listed in the Modified PTO Form 1449 submitted May 12, 2003 that apparently are not in the PTO's possession. The attached List of References Cited contains an identical listing of references as in the Modified PTO Form 1449 of May 12, 2003 with the exception that the Foreign Patent Documents are now listed chronologically in order of publication date and the Non-Literature Patent Documents, originally captioned "Other Documents" 05/23/2006 FMETEKI1 00000023 503013 are now listed in alphabetical order by author.

Identification of the listed references is not to be construed an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application.

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(c)(2), since this Information Disclosure Statement is being submitted after the first Office Action on the Merits but before a final Office Action under 37 C.F.R. § 1.113, a fee of \$180.00 is believed due. Please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: May 19, 2006

32,605

Reg. No.)

M. anter

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LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

	ATTY. DOCKET NO. 8449-429-999	APPLICATION NO. 10/053,520
	APPLICANT Rothman et al.	
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		U.S. PATEN	T DOCUMENTS	
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR

	FOREIGN PATENT DOCUMENTS					
		FOREIGN PATENT DOCUMENT COUNTRY CODE, NUMBER, KIND CODE (IF KNOWN)	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR	
	B01	EP 0 538 952	04/28/93	Yeda Research and Development Co. Ltd.		
	B02	WO 89/04871	06/01/89	Imperial Cancer Research Technology Limited		
-	B03	WO 93/17712	09/16/93	Biocine Scalvo Spa		
	B04	WO 94/11513	05/26/94	Medical Research Council		
	B05	WO 94/29459	12/22/94	Whitehead Research for Biomedical Research		
	B06	WO 95/24923	09/21/95	Mount Sinai School of Medicine at the City University of New York		
	B07	WO 96/10411	04/11/96	Mount Sinai School of Medicine at the City University of New York		
	B08	WO 97/06821	02/20/97	Sloan-Kettering Institute for Cancer Research		
	B09	WO 97/06685	02/27/97	Sloan-Kettering Institute for Cancer Research		
	B10	WO 97/10000	03/20/97	Fordham University		
	B11	WO 97/10001	03/20/97	Fordham University		
	B12	WO 97/10002	03/20/97	Fordham University		
	B13	WO 97/26910	07/31/97	Max-Delbruck Centrum for Molekulare Medizin		
	B14	WO 98/23735	06/04/98	Stressgen Biotechnologies Corp.		
	B15	WO 98/35705	08/20/98	Whitehead Research for Biomedical Research		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)		
	C01	ARNOLD et al., 1995, "Cross-priming of Minor Histocompatibility Antigen-specific Cytotoxic T Cells upon Immunization with the Heat Shock Protein gp96." J. Exp. Med. 182:885-9.		

EXAMINER	DATE CONSIDERED

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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xaminer nitials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)
intiais	C02	AUGER et al., 1996, "HLA-DR4 and HLA-DR10 motifs that carry susceptibility to rheumatoid arthritis bind 70-kD heat shock proteins." Nature Medicine 2:306-310.
	C03	BARRIOS et al., 1992, "Mycobacterial heat-shock proteins as carrier molecules. II: The use of the 70-kDa mycobacterial heat-shock protein as carrier for conjugated vaccines can circumvent the need for adjuvants and Bacillus Calmette Guerin priming." Euro. J. Immunol. 22:1365-1372.
	C04	BARRIOS et al., 1994, "Specificity of antibodies induced after immunization of mice with the mycobacterial heat shock protein of 65 kD." Clin. Exp. Immunol. 98:224-228.
	C05	BARRIOS et al., 1994," Heat shock proteins as carrier molecules: in vivo helper effect mediated by Escherichia coli GroEL and DnaK proteins requires cross-linking with antigen." Clin. Exp. Immunol. 98:229-233.
	C06	BAUER et al., 1995, "Identification of H-2Kb binding and immunogenic peptides from human papilloma virus tumour antigens E6 and E7." Scand. J. Immunol. 42:317-323.
	C07	BLACHERE & SRIVASTAVA, 1995, "Heat shock protein-based cancer vaccines and related thoughts on immunogenicity of human tumors." Seminars in Cancer Biology 6:349-355.
	C08	BLACHERE et al., 1997, "Heat shock protein-peptide complexes, reconstituted in vitro, elicit peptide-specific cytotoxic T lymphocyte response and tumor immunity." J. Exp. Med. 186:1315-1322.
-	C09	BLOND-ELGUINDI et al., Affinity Panning of a Library of Peptides Displayed on Bacteriophages Reveals the Binding Specificity of BiP." Cell 75:717-728 (1993).*
	C10	CZAR et al., 1997, "Geldanamycin, a heat shock protein 90-binding benzoquinone ansamycin, inhibits steroid-dependent translocation of the glucocorticoid receptor from the cytoplasm to the nucleus." Biochemistry 36:7776-7785.
-	C11	DAVIDOFF et al., 1992, "Immune response to p53 is dependent upon p53/HSP70 complexes in breast cancers." Proc. Natl. Acad. Sci. USA 89:3439-3442.
	C12	DEL GUIDICE, 1994, "Hsp70: a carrier molecule with built-in adjuvanticity." Experientia 50:1061-1066.
	C13	DeNAGEL & PIERCE et al., 1993, "Heat shock proteins in immune responses." Critical Reviews In Immunology 13:71:81.
	C14	DILLMAN et al., 1995, "Heat Shock Proteins and Ischemic Injury." J. Cell. Biochem., Suppl. 19B, p. 190.
	C15	EDGINGTON, 1995, "Therapeutic applications of heat shock proteins." Biotechnol. 13:1442-1444.
	C16	FLYNN et al., 1989, "Peptide-dependent stimulation of the ATPase activity of the molecular chaperone BiP is the result of conversion of oligomers to active monomers." Science 245:385-390.
	C17	GALIGNIANA et al., 1998, "Heat shock protein 90-dependent (geldanamycin-inhibited) movement of the glucocorticoid receptor through the cytoplasm to the nucleus requires intact cytoskeleton." Mol. Endo. 12:1903-1913.
	C18	GETHING, et al., 1995, "Binding Sites for Hsp70 Molecular Chaperones in Natural Proteins." Cold Spring Harb. Symp. Quant. Biol. 60:417-28.
	C19	GIBOA, 1996, "Immunotherapy of cancer with gengetically modified tumor vaccines." Seminars in Oncology 23:101-107.
	C20	GRAGEROV et al., 1994, "Different peptide binding specificities of hsp70 family members." J. Mol. Biol. 235:133-135.
	C21	GRAGEROV et al., 1994, "Specificity of DnaK-peptide binding." J. Mol. Biol. 235:848-854.
-	C22	GREENE et al., 1995, "Effect of nucleotide on the binding of peptides to 70-kDa heat shock protein." J. Biol. Chem. 270(7):2967-2978.

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•		NON PATENT LITERATURE DOCUMENTS
Examiner nitials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)
iitiais	C23	HOHFELD et al., 1995, "Hip, a novel cochaperone involved in the eukaryotic Hsc70/Hsp40 reaction cycle." Cell 83:589-598.
	C24	JAATTELA, 1995, "Over-expression of hsp70 confers tumorigenicity to mouse fibrosarcoma cells." Int. J. Cancer, 60 (5), pp. 689-693.
	C25	JAKOB et al., 1996, "Assessment of the ATP binding properties of Hsp90." J. Biol. Chem. 271:10035-10041.
	C26	JINDAL, S., 1996, "Heat shock proteins: applications in health and disease." Trends Biotechnol. 14:17-20.
	C27	LI, Z. et al., 1993, "Tumor rejection antigen gp96/grp94 is an ATPase: implications for protein folding and antigen presentation." EMBO J. 12:3143-51.
-	C28	LITTLE, et al., 1994, "The glucose-regulated proteins (GRP78 and GRP94): functions, gene regulation, and applications." Critical Reviews in Eukaryotic Gene Expression, 1994 4(1) pp. 1-18.
-	C29	LOWRIE et al., 1994, "Towards a DNA vaccine against tuberculosis." Vaccine 12:1537-1540.
	C30	LOWRIE et al., 1995, "Mycobacterium Leprae HSP65 Vaccinates mice against Tuberculosis when Expressed from the Cloned Gene in Transplanted Bone Marrow Cells." J. Cell. Biochem. Suppl. 0(19b):220.
	C31	LUKACS et al., 1993, "Tumor cells transfected with a bacterial heat-shock gene lose tumorigenicity and induce protection against tumors." J. Exp. Med. 178:343-348.
	C32	LUKACS et al., 1994, "Protection against tumours by mycobacterial heat shock protein gene." Cancer Gene Therapy, 1:217.
	C33	LUSSOW et al., 1991, "Mycobacterial heat-shock proteins as carrier molecules." J. Eur. Immunol. 21:2297-2302.
· <u> </u>	C34	MASTRANGELO et al., 1996, "Gene therapy for human cancer: an essay for clinicians." Seminars in Oncology, 23:4-21.
	C35	MCCARTY et al., 1995, "The role of ATP in the functional cycle of the DnaK chaperone system." J. Mol. Biol. 249:126-137.
	C36	MELNICK, et al., 1992, "The endoplasmic reticulum stress protein GRP94 in addition to BiP, associates with unassembled immunoglobulin chains." J. of Biochem. 267:21303-21306.
	C37	MINAMI et al., 1996, "Regulation of the heat-shock protein 70 reaction cycle by the mammalian DnaJ homolog, Hsp40." J. Biol. Chem. 271:19617-19624.
	C38	MOROI, 2000, "Induction of cellular immunity by immunization with novel hybrid peptides complexed to heat shock protein 70." Proc Natl Acad Sci U S A 97(7):3485-90
	C39	MULTHOFF et al., 1995, "A stress-inducible 72-kDa heat-shock protein (HSP72) is expressed on the surface of human tumor cells, but not on normal cells." Int. J. Cancer 61:272-279.
	C40	MUNRO AND PELHAM, 1987, "A C-terminal signal prevents secretion of luminal ER proteins." Cell, 480:899-907.
*	C41	MUSTAFA et al., 1993, "Human T cells recognize mycobacterial heat shock proteins in the context of multiple HLA-DR molecules: studies with healthy subjects vaccinated with Mycobacterium bovis BCG and Mycobacterium leprae." Infection and Immunity 61:5294-5301.
	C42	NADEAU et al., 1992, "83-kilodalton heat shock proteins of trypanosomes are potent peptide-stimulated ATPases." Protein Science 1:970-979.
	C43	NADEAU et al., 1992, "Hsp90 chaperonins possess ATPase activity and bind heat shock transcription factors and peptidyl prolyl isomerases." J. Biol. Chem. 268:1479-1487.
	C44	NIELAND et al., 1996, "Isolation of an immunodominant viral peptide that is endogenously bound to the stress

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		protein GP96/GRP94." Proc. Natl. Acad. Sci. USA 93:6135-6139.
	C45	NYGREN et al., 1994, "Engineering proteins to facilitate bioprocessing." Trends Biotechnol. 12(5):184-188.
· · · · ·	C46	PALLEROS et al., 1993, "ATP-induced protein-Hsp70 complex dissociation requires K+ but not ATP hydrolysis." Nature 365:664-666.
	C47	PARDOLL, 1993, "New strategies for enhancing the immunogenicity of tumors." Current Opinion in Immunology 5:719-725.
	C48	PELHAM, 1988, "Evidence that luminal ER proteins are sorted from secreted proteins in a post-ER compartment." EMBO J. 7:913-918.
-	C49	PERRAUT, 1993, "Successful primate immunization with peptides conjugated to purified protein derivative or mycobacterial heat shock proteins in the absence of adjuvants." Clin. Exp. Immunol. 93:382-386.
· ·	C50	PIDOUX et al., 1992, "Analysis of the BiP gene and identification of an ER retention signal in Schizosaccharomyces pombe." EMBO J. 11:1583-1591.
	C51	PLUMIER et al., 1995, "Transgenic mice expressing the human heat shock protein 70 have improved post-ischemic myocardial recovery." J. Clin. Invest. 95 (4), pp. 1854-1860.
	C52	PORGADOR et al., 1994, "Immunotherapy of tumor metastasis via gene therapy." Nat. Immun. 13:113-130.
	C53	RETZLAFF et al., 1994, "Bacterial heat shock proteins directly induce cytokine mRNA and interleukin-1 secretion in macrophage cultures." Infect. Immun. 62:5689-5693.
	C54	RIDDELL et al., 1996, "T-cell mediated rejection of gene-modified HIV-specific cytotoxic T lymphocytes in HIV-infected patients." Nature Medicine 2:216-223
	C55	ROSENBERG et al., 1996, "T7 Select Phage Display System: A powerful new protein display system based on Bacteriophage T7," inNovations (newsletter of Novagen, Inc.) No. 6, pp. 1-6.
<u> </u>	C56	SATO et al., 1994, "70 kDA heat shock protein as a tumor antigen and a target for the host's anti-tumor resistance by cytotoxic T lymphocytes." Proc. Annu. Meet. Am. Assoc. Cancer Res. 35:A2959.
	C57	SCHMID et al., 1994, "Kinetics of molecular chaperone action." Science 263:971-973.
	C58	SILVA AND LOWRIE, 1994, "A single mycobacterial protein (hsp 65) expressed by a transgenic antigen- presenting cell vaccinates mice against tuberculosis." Immunology 82:244-248.
	C59	SRIVASTAVA & MAKI, 1991, "Stress-induced proteins in immune response to cancer." Current Topics in Microbiology and Immunology 167:109-123.
	C60	SRIVASTAVA and UDONO, 1994, "Heat shock protein-peptide complexes in cancer immunotherapy." Curr. Opin. Immunol. 6(5):728-732
 	C61	SRIVASTAVA et al., 1986, "Tumor rejection antigens of chemically induced sarcomas of inbred mice." Proc. Natl. Acad. Sci. USA 83:3407-3411.
	C62	SRIVASTAVA, 1993, "Peptide-binding heat shock proteins in the endoplasmic reticulum: role in immune response to cancer and in antigen presentation." Adv. Cancer Res. 62:153-177.
	C63	SRIVASTAVA, 1994, "Heat shock proteins in immune response to cancer: the Fourth Paradigm." Experentia 50:1054-1060.
	C64	SUTO, et al., 1995, "A Mechanism for the Specific Immunogenicity of Heat Shock Protein-Chaperoned Peptides." Science 269:1585-7.
	C65	SUZUE, et al., 1996, "Adjuvant-Free hsp Fusion Protein System Elicits Humoral and Cellular Immune Responses to HIV-1 p24.sup.1." J. Immunol. 156:873-9.
	C66	TAMURA et al., 1997, "Immunotherapy of tumors with autologous tumor-derived heat shock protein

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		preparations." Science 278:117-120.			
• • • • • • • • • • • • • • • • • • • •	C67	TARPEY, I. et al., 1994, "Human cytotoxic T lymphocytes stimulated by endogenously processed human papillomavirus type 11 E7 recognize a peptide containing a HLA-A2 (A*0201) motif." Immunology 81:222-7.			
	C68	TAVARIA et al., 1996, "Cell Stress and Chaperones 1:23-28." Cell Stress and Chaperones 1:23-28.			
	C69	UDONO et al., 1994, "Comparison of tumor-specific immunogenicities of stress-induced proteins gp96, hsp90, and hsp70." J. Immun. 152, pp. 5398-5403.			
-	C70	UDONO, et al., 1993, "Heat shock protein 70-associated peptides elicit specific cancer immunity." J. Exp. Med. 178:1391-6.			
	C71	UDONO, et al., 1994, "Cellular requirements for tumor-specific immunity elicited by heat shock proteins: Tumor rejection antigen gp96 primes CD8+ T Cells in vivo." Pro. Natl. Acad. Sci. 91:3077-81.			
	C72	ULLRICH et al., 1986, "A mouse tumor-specific transplantation antigen is a heat shock-related protein." Proc. Natl. Acad. Sci. USA 83:3121-3125.			
	C73	VON HEIJNE, 1985, "Signal sequences. The limits of variation." J. Mol. Biol. 184:99-105.			
	C74	WEARSCH et al., 1997, "Interaction of endoplasmic reticulum chaperone GRP94 with peptide substrates is adenine nucleotide-independent." J. Biol. Chem. 272:5152-5156.			
	C75	WHITESELL, et al., 1994, "Inhibition of heat shock protein HSP90-pp60v-src heteroprotein complex formation by benzoquinone ansamycins: essential role for stress proteins in oncogenic transformation." Proc. Natl. Acad. Sci. USA 91:8324-8328.			
	C76	YAMAMOTO et al., 1993, "Listeria monocytogenes-induced gamma interferon secretion by intestinal intraepithelial gamma/delta T lymphocytes." Infection and Immunity 61:2154-2161.			
	C77	ZHU et al., 1995, "Both immunization with protein and recombinant vaccinia virus can stimulate CTL specific for the E7 protein of human papilloma virus 16 in H-2d mice." Scand. J. Immunol. 42:557-563.			
•	C78	ZHU et al., 1996, "Structural analysis of substrate binding by the molecular chaperone DnaK." Science 272:1606-1614.			

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